

U.S. Patent Application Serial No. **10/535,422**
Amendment filed March 2, 2010
Reply to OA dated November 2, 2009

REMARKS

Claims 1-7, 11-14, 16 and 18 are pending in this application. Claims 4 and 11 are canceled without prejudice or disclaimer, claim 1 is amended herein. Upon entry of this amendment, claims 1-3, 5, 6, 12-14, 16 and 18 will be pending. Entry of this amendment and reconsideration of the rejections are respectfully requested.

No new matter has been introduced by this Amendment. Support for the amendment to claim 1 is discussed below.

Claims 1-7, 11-14, 16 and 18 are rejected under 35 U.S.C. §103(a) as being unpatentable over Berns (U.S. Patent No. 5,503,687) in view of Wikipedia (http://en.wikipedia.org/wiki/Ferritic_stainless_steel) and further in view of Gordon (U.S. Pub. No. 2002/0133225 A1). (Office action paragraph no. 3)

Reconsideration of the rejection is respectfully requested in view of the amendment to claim 1. As amended, claim 1 clarifies the order of the steps, requiring the nitrogen absorption step after the working step. The amendment also incorporates the treatment temperature limitation of claim 4, which has accordingly been canceled without prejudice or disclaimer.

Applicant notes that the corresponding Japanese Patent Application (JP Patent Number 4336784) to the present application has been patented with claim 1 amended as in the present amendment.

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In arguing against the rejection, Applicant first of all again argues that the Wikipedia citation is not a proper prior art reference. In the Office action, the Examiner states that the Wikipedia reference is simply a review citing older references that are prior art. The Office Action asserts that Wikipedia discloses having very little nickel content (refer to page 4 of the Office Action).

However, Applicant respectfully notes that the content of the Wikipedia article can be seen to significantly change, and again argues that Wikipedia cannot be considered to be a proper reference. For example, the Wikipedia article stated that:

"They contain between 10.5% and 27% chromium and very little nickel, if any, but some types can contain lead. Most compositions include molybdenum; some aluminum or titanium. Common ferritic grade include 18Cr-2Mo, 26Cr-1Mo, 29Cr-4Mo, and 29Cr-4Mo-2Ni" (content on September 9, 2009)

However, on November 22, 2009, the Wikipedia article stated that:

"These, alloys can be degraded by the presence of σ chromium, an intermetallic phase which can precipitate upon welding."

It is apparent from this that the content of this Wikipedia article changes from time to time, and its content is not definite. It cannot be relied on as a reference.

In regard to the rejection as stated, Applicant respectfully submits that the Examiner's argument with regard to a *prima facie* case of anticipation or obviousness (pages 2-3 of Office action) is improper. The Examiner states that: "in the instant case, the claimed and Berns ('667) in view of Wikipedia and further in view of Gordon's stents are identical or substantially identical in terms of structure or composition" However, this argument is generally applicable only to

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product claims, for which patentability is determined by the structure/composition, and not to the method by which the product is made. Claim 1 is a **method** claim, and it is the obviousness of the **method steps**, not merely the end product, that is at issue.

Paragraph [0032] of the present application recites that:

"in the present embodiment, the material is worked to a medical device body, then the worked product is made to absorb nitrogen so as to transform at least part to austenite. Therefore, by performing a step requiring workability by the **ferritic stainless steel material**, working this to a medical device, then transforming this to austenite, it becomes possible to provide a product able to be worked on a complicated medical device and superior in corrosion resistance and safety." (emphasis added)

As evident from the above, the present invention starts from a ferritic stainless steel, and all of the ferritic stainless steel is changed to austenite.

In contrast to this, column 1, lines 49 to 56, of Berns discloses that the core can be ferrite, austenitic, martensite, or a mixture of two or three of those. Hence, if the core of Berns is ferritic, the finished product of Berns will have two phases: that is, ferrite core and austenite surface; in this case, Berns and the present invention will differ in the structure of the end product. Similarly, if the core of Berns is austenite, the finished product will be entirely austenite; however, in this case Berns and the present invention differ in the starting material.

In either case, the method of Berns and that of the pending claims are fundamentally different.

Furthermore, since in the present invention, the ferritic stainless steel forming the medical device body absorbs nitrogen to transform all of the ferritic stainless steel tube to austenite (claim

1 of the present application), the present invention has no magnetic property. In contrast to this non-magnetic property, the invention disclosed in Gordon is characterized in having a ferromagnetic property.

That is, the properties of the present invention are the opposite of those required by Gordon, and Applicant submits that Berns and Gordon cannot be combined as proposed by the Examiner. The material cited in Gordon is a ferromagnetic material, which in Gordon is selected specifically for its magnetic property. That is, in Gordon, the ferritic stainless steel is selected specifically so that it can be magnetized: "... the stent 10 becomes magnetized" (see paragraph [0057]). This magnetic field is used to localize delivery of superparamagnetic iron oxide nanoparticles containing taxol (see paragraph [0058]). However, the Examiner's proposed modification by the nitrogen enrichment treatment of Berns, leading to an austenitic surface layer, would, in fact, **impede** the magnetic property, since austenitic steel does not have good magnetic properties. That is, the Examiner's proposed modification of Gordon would render Gordon's stent unmagnetizable and unusable for Gordon's purpose, and this argues against the motivation for the combination of the references. Note that MPEP 2143.01(V) states:

If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)


Applicant therefore submits that the pending claims, as amended, are not obvious over Berns, Wikipedia and Gordon, taken separately or in combination.

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If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact the applicants' undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

In the event that this paper is not timely filed, the applicants respectfully petition for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,
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Enclosures: Request for Continued Examination (RCE)
Petition for Extension of Time
Information Disclosure Statement

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